Citation:

Flechtner-Mors M, Biesalski HK, Jenkinson CP, Adler G, Ditschuneit HH. Effects of moderate consumption of white wine on weight loss in overweight and obese subjects. *Int J Obes Relat Metab Disord*. 2004 Nov; 28 (11): 1,420-1,426.

PubMed ID: <u>15356671</u>

Study Design:

Randomized Controlled Trial

Class:

A - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To investigate the effectiveness of an energy-restricted diet on weight loss in overweight and obese subjects who regularly consume moderate amounts of alcohol
- To investigate whether there was any impairment of the effectiveness of the diet in subjects consuming alcohol during dietary treatment compared to subjects with no alcohol consumption
- To examine whether there were any differences between the diet groups in weight loss, and biochemical health parameters between groups after a three-month intervention.

Inclusion Criteria:

- \bullet Men and women ages 18 years and older with body mass index (BMI) between 25.0 and $40.0 kg/m^2$
- Had to regularly consume 20-30g of alcohol per day
- Be willing to be randomly assigned to study groups and to follow the program protocol.

Exclusion Criteria:

- Had a history of significant disease, endocrine disorders, psychiatric disease, alcohol or drug abuse, abnormal laboratory test results of clinical significance
- Women who are lactating, pregnant or wish to become pregnant.

Description of Study Protocol:

Recruitment

• Participants were recruited from the Obesity Center at the outpatient clinic of the University Hospital

• All subjects enrolled in the study were wine-drinkers.

Design

This study was a prospective parallel (randomized) intervention trial.

Dietary Intake/Dietary Assessment Methodology

Seven-day dietary diaries collected.

Blinding Used

Not applicable.

Intervention

Participants were randomized to two different 1,500kcal per day diets, with either grape juice group (10% of total energy derived from grape juice) or white wine group (10% of total energy derived from white wine).

Statistical Analysis

Comparisons were made between groups (grape juice and white wine). These comparisons were made using two sample T-test, paired T-test (looking for significant changes from baseline to three months) for each group. Two-sample T-test were performed to compare the three-month changes between grape juice group and white wine group.

Data Collection Summary:

Timing of Measurements

Three months.

Dependent Variables

- Variable 1: Body weight (measured by use of precision scale made at each visit)
- Variable 2: Waist circumference (measured using non-stretchable tape made at each visit)
- Variable 3: Hip circumference (measured using non-stretchable tape made at each visit)
- Variable 4: Blood pressure (measured using a mercury column manometer made at each visit)
- Variable 4: Biochemical measure for liver function test (ALT, AST, AP, GT) (measured using routine methods made at baseline and after three months)
- Variable 5: Biochemical measures for creatinine (measured using routine methods made at baseline and after three months)
- Variable 6: Biochemical measures for leukocytes, erythrocytes, and hemoglobin (measured using routine methods made at baseline and after three months)
- Variable 7: Biochemical measures for blood lipids including total cholesterol=, HDL cholesterol, LDL cholesterol, triglycerides using enzymatic colorimetric methods using kits made at baseline and after three months)
- Variable 8: Biochemical measures for blood glucose (measure enzymatically and amperometrically made at baseline and after three months)
- Variable 9: Biochemical measures for fibrinogen, uric acid and leukocytes (measured using standard measures made at baseline and after three months)

• Variable 10: Biochemical measures for Vitamin C (measure by ESR-Spectroscopie using MiniScope MS 200 made at baseline and after three months).

Independent Variables

Dietary intake:

- Each participant meet with an RD who designed the diet regimen, explained the diet plan in detail and counseled
- Each participant consumed a balanced diet providing 1,500kcal per day (15% of energy from protein, 30-35% of energy from fat, and energy from carbohydrates at 50-55% of of total kcal intake including grape juice or 45-50% of energy as carbohydrates and approximately 10% of energy from white wine (making it so that 10% of energy came from either grape juice or white wine).

Control Variables

No controls noted.

Description of Actual Data Sample:

- *Initial N*: 49 males and females
- Attrition (final N):
 - 40 (although some of the initial eligible participants dropped out and were replaced to ensure that 20 participants would be in each intervention group grape juice or white wine and that each participant complete the three-month intervention period)
 - 18% attrition
- Age: 18 years and older; Mean: 48.1±11.4 years
- Ethnicity: No indication of ethnicity
- Other relevant demographics: No statistical difference between participants randomized to each group for age, body weight or BMI
- ullet Anthropometrics:
 - No statistical difference between participants randomized to each group for age, body weight, or BMI
 - Mean BMI: 34.2±6.4kg/m²
- Location: Germany.

Summary of Results:

Key Findings

- While participants assigned to grape juice (GJ) group had a lower BMI and lower age than those in the white wine (WW) group, there were no statistically significant differences noted between the groups at baseline
- All participants lost weight on the energy-restricted diets
- The GJ group lost 3.75±0.46kg (range 0.90-8.00kg) or 4.0% of initial body weight (P<0.001)
- The WW group lost 4.73±0.53kg (range 0.90-11.70kg) or 4.88% of initial body weight (P<0.001)
- The weight lost in the WW group was 26.1% higher than in the GJ group, but the difference

- was not significant
- Statistically significant differences between the GJ group and the WW group in other anthropometic measures were not observed
- Subjects adhered to the dietary changes requested based on the seven-day diary analysis.

Table: Selected Anthropometric Parameters of Obese Subjects At The Beginning of the Study and After Three Months of Treatment With An Energy-restricted Diet With Grape Juice (N=20) Or White Wine (N=20)

Variables	Grape Juice	Grape Juice	White Wine	White Wine	
	Before	After Three Months	Before	After Three Months	
Body Weight (kg)	93.3±4.7	89.5±4.6*	96.9±4.0	92.2±3.9*	
BMI (kg/m ²)	33.2±1.5	31.9±1.5*	35.2±1.2	33.5±1.2*	

^{*}P<0.05 vs. baseline.

Author Conclusion:

- The author concluded that an energy-restricted diet was effective in overweight and obese subjects who habitually consumed moderate amounts of alcohol and who maintained their habit during treatment with an energy-restricted diet
- Also indicated by the author is the idea that the study was done with white wine and overweight and obese healthy subjects and may not be applicable to all alcoholic beverages and to normal-weight individuals or subjects that have underlying diseases
- The author further indicated that there is a need to investigate the long-term effect of moderate alcohol consumption on weight loss and weight maintenance with a greater number of subjects to confirm and clarify the findings.

Reviewer Comments:

- The study did not adequately explain actual timing of data collection (in the body composition measures)
- Study supported by grants from Deutsche Weinakademie GmbH and Forum Wein und Gesundheit (both wine-related organizations).

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)



	2.	the patients/clients/population group would care about?			
	3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes		
	4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes		
Vali	dity Questions				
1.	Was the res	Was the research question clearly stated?			
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes		
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes		
	1.3.	Were the target population and setting specified?	Yes		
2.	Was the seld	ection of study subjects/patients free from bias?	Yes		
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes		
	2.2.	Were criteria applied equally to all study groups?	Yes		
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes		
	2.4.	Were the subjects/patients a representative sample of the relevant population?	No		
3.	Were study	groups comparable?	Yes		
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes		
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes		
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes		

If cohort study or cross-sectional study, were groups comparable

on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in N/A

statistical analysis?

3.4.

	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	l of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	No
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	???
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	No
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		ention/therapeutic regimens/exposure factor or procedure and ison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcom	nes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the stat outcome ind	istical analysis appropriate for the study design and type of icators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	No
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusi consideration	ons supported by results with biases and limitations taken into n?	Yes
	9.1.	Is there a discussion of findings?	Yes

	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	10. Is bias due to study's funding or sponsorship unlikely?		No
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	No